Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 30-71 are pending in the application, with claims 30, 40, 55, 66, 68, 69 and 70 being the independent claims. Claims 30, 34, 36-38 and 40 are amended. New claims 42-71 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Telephone interview of July 23, 2002

Applicants' representative thanks the Examiner for the courtesies extended during the telephone interview. During the interview, the Examiner indicated that the proposed amendments to claim 30 and 40 would likely overcome the cited reference, although further review may be necessary.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 30-39 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claims 30 and 37 have been amended to correct minor informalities, and to provide appropriate antecedent basis. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 30-36, 40 and 41 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by *Ruggio*, U.S. Patent No. 5,476,450. As discussed during the telephone interview, claim 30 has been amended to recite the coaxial arrangement of the guide catheter, the leading guide wire, and the infusion guide wire. Applicants respectfully direct the Examiner's attention to *Ruggio*, and specifically, to Figures 8A-8C and 15, and the corresponding text in the specification of *Ruggio*, which show that *Ruggio* does not disclose the coaxial arrangement of the guide catheter, the infusion guide wire, and the leading guide wire. Accordingly, every element of claim 30, as amended, is not taught or suggested by *Ruggio*, and Applicants respectfully request that the rejections under 35 U.S.C. § 102(b) be withdrawn.

Claims 31-36 depend from claim 30, and are allowable at least for the same reasons as those applicable to independent claim 30, as well as for the features recited therein.

Claim 40 stands rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by *Ruggio*. Claim 40 has been amended to recite "a hollow leading guide wire". Support for the language of the amendment may be found, for example, at page 16, lines 16-22 of the specification. This aspect of the invention of claim 40 is not taught or suggested by *Ruggio*. Accordingly, *Ruggio* does not anticipate the invention of amended claim 40. Therefore, Applicants respectfully request that the rejection of claim 40 under 35 U.S.C. § 102(b) be withdrawn.

Claim 41 depends from independent claim 40, and is allowable at least for the reasons applicable to claim 40, as well as for the features recited therein.

Rejections under 35 U.S.C. § 103(a)

Claims 37-39 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over *Ruggio*. Since these claims depend from independent claim 30, they are allowable at least for the reasons applicable to claim 30, as well as due to the features recited therein. Accordingly, Applicants respectfully request that the rejections of claims 37-39 under 35 U.S.C. § 103(a) be withdrawn.

New claims 42-71

New claims 42-71 are added to provide additional coverage for the present invention. Support for the language of these claims may be found in originally filed claims 30-41, figures 4 and 10 of the present application, page 15, lines 4-8 and page 16, lines 16-22 of the specification, and as further discussed below.

Claims 42-53 are allowable at least for the reasons discussed above with reference to claim 30.

Newly added independent claim 54 recites a combination "wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability to penetrate the wall of the right atrium without kinking . . . ." This combination is not disclosed by *Ruggio*. *Ruggio* does not disclose the use of its catheter to penetrate into the pericardial space from inside a the right atrium. Applicants note that the Office Action, at page 3, appears to suggest that *Ruggio*, at col. 9, lines 42-44, discloses that the catheter of *Ruggio* may be used for this purpose. Respectfully, this is incorrect, since *Ruggio* mentions aspiration **within a heart chamber, but not penetrating the pericardial**

space, which is an entirely different, and highly specific application for which conventional catheters, such as in *Ruggio*, are not designed.

Furthermore, Applicants respectfully submit that a guide wire having inadequate pushability, stiffness or flexibility will result in either kinking of the guide wire (possibly rupturing the myocardial wall), or in an inability to deliver the guide wire to the proper location in the heart. Improper selection can result in trauma to the heart wall -- a crucial concern during an operation. Because *Ruggio* fails to address the highly specific application and concerns at issue to which claim 55 is directed–accessing the pericardial space by penetrating the myocardial wall–*Ruggio* fails to teach or suggest the guide wire as recited in claim 55.

Claims 56-65 depend from claim 55, and are allowable at least for the same reasons as those applicable to independent claim 55, as well as for the features recited therein.

Newly added independent claim 66 is directed to a "dual guide wire for transvenously accessing a pericardial space between a heart and its pericardium **to perform a surgical procedure on the heart.**" (Emphasis added.) Support for the language of this claim may be found, for example, at page 6, line 13 and page 22, line 4 of the specification. This is a highly specific application not taught or suggested by *Ruggio*. (See also dependent claim 46, which also recites this aspect.)

Newly added independent claim 68 is directed to a combination "wherein said dual guide wire has sufficient pushability to penetrate into the pericardial space through a wall of a right atrium of the heart without kinking, and **has sufficient steerability to be steered to any location within the pericardium.**" (Emphasis added.) Support for the

language of this claim may be found, for example, at page 6, line 23 and page 22, line 24 of the specification. This is also a highly specific application not taught or suggested by *Ruggio*. (See also dependent claim 45, which also recites this aspect.)

Newly added independent claim 69 recites a combination including "an infusion guide wire for aspiration of fluid from the pericardial space to treat cardiac tamponade; a leading guide wire . . . wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability to penetrate the wall of the right atrium into the pericardial space without kinking." At least this combination is not disclosed by *Ruggio*. *Ruggio* fails to disclose an infusion guide wire that is **suitable for aspiration of fluid from the pericardial space to treat cardiac tamponade**. See, e.g., page 22, line 22 of the specification and originally filed claim 23. Furthermore, as discussed above, *Ruggio* fails to disclose a catheter with guide wires whose joint properties are suitable for penetrating the myocardial wall into the pericardial space. See generally page 25, lines 23-29 of the specification.

Newly added independent claim 70 is directed to a "dual guide wire for transvenously accessing a pericardial space between a heart and its pericardium to implant a surgical device within the heart." Support for the language of this claim may be found, for example, at page 14, line 4 and page 22, line 7 of the specification. This is also a highly specific application not taught or suggested by *Ruggio*. (See also dependent claim 47, which also recites this aspect.)

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

Please amend claims 30, 34, 36-38 and 40 as follows:

30. (Amended) A kit for transvenously accessing the pericardial space between a heart and its pericardium to perform a medical procedure on the heart, the kit comprising:

a guide catheter;

an infusion guide wire coaxial with said guide catheter substantially throughout a length of said guide catheter; and

a leading guide wire coaxial with said infusion guide wire and having a diameter sufficiently small to be passed through a lumen of said infusion guide wire, said leading guide wire having a sufficient length to pass through and protrude from a distal end of said infusion guide wire, and having a distal end capable of penetrating a wall of the right atrium of the subject's heart,

wherein said infusion guide wire and said leading guide wire both have sufficient flexibility to permit said infusion guide wire and said leading guide wire to be simultaneously passed through said guide catheter into the right atrium of the subject's heart via a transvenous route.

34. (Amended) The kit of claim 33, [further comprising:] wherein said infusion guide wire functions as an aspiration catheter having a lumen of sufficient diameter so that said [aspiration catheter] infusion guide wire may be passed over said [infusion] leading guide wire and into the pericardial space for the removal of fluid from the pericardial space to treat cardiac tamponade.

36. (Amended) The kit of claim 35, [further comprising:] wherein said infusion guide wire functions as an aspiration catheter having a lumen of sufficient diameter so that said [aspiration catheter] infusion guide wire may be passed over said leading guide wire and into the pericardial space for the removal of fluid from the pericardial space to treat cardiac tamponade.

37. (Amended) The kit of claim 30, wherein said leading guide wire has a diameter between 0.010 inches and 0.018 inches.

38. (Amended) The kit of claim 36, wherein said leading guide wire has a diameter of 0.014 inches.

40. (Amended) A kit for transvenously accessing the pericardial space between a heart and its pericardium to perform a medical procedure on the heart, the kit comprising:

a guide catheter having sufficient length and flexibility to be inserted into the right atrium of a subject's heart via a transvenous route;

an infusion guide wire within said guide catheter and having sufficient stiffness to traverse a patient's anatomy to be inserted into the right atrium of a subject's heart via a transvenous route;

a hollow leading guide wire extending through said guide catheter and having a diameter sufficiently small to be passed through a lumen of said guide catheter,

wherein said leading guide wire has sufficient length to pass through and protrude from a distal end of said guide catheter, a distal end capable of penetrating a wall of the right atrium of the subject's heart, and sufficient flexibility to permit said leading guide wire to be passed through said guide catheter and into the right atrium of the subject's heart via a transvenous route.

Please add new claims 42-71 as follows:

42. (New) The kit of claim 30, wherein said infusion guide wire further comprises a radiopaque marker on its distal end.

43. (New) The kit of claim 30, wherein said guide catheter further comprises a radiopaque marker on its distal end.

44. (New) The kit of claim 30, wherein said leading guide wire further comprises a radiopaque marker on its distal end.

45. (New) The kit of claim 30, wherein said leading guide wire is steerable to any location within the pericardium.

46. (New) The kit of claim 30, wherein said kit is adapted to perform a surgical procedure on the heart.

47. (New) The kit of claim 30, wherein said kit is adapted for placing an implantable device into the pericardium.

48. (New) The kit of claim 30, further including a locking device to fix a relative position of the leading guide wire relative to the infusion guide wire.

49. (New) The kit of claim 30, wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability to penetrate into the pericardial space through a wall of a right atrium of the heart without kinking.

50. (New) The kit of claim 30, wherein said infusion guide wire has a lumen of sufficient diameter for passing a fiberoptic imaging probe into the pericardium.

51. (New) The kit of claim 30, wherein said guide catheter further comprises a blood pressure monitor.

52. (New) The kit of claim 30, wherein said guide catheter further comprises an ECG monitor.

53. (New) The kit of claim 30, wherein said infusion guide wire further comprises at least one electrode.

54. (New) The kit of claim 30, wherein said leading guide wire further comprises at least one electrode.

55. (New) A dual guide wire for transvenously accessing a pericardial space between a heart and its pericardium to perform a medical procedure on the heart comprising:

an infusion guide wire; and

a leading guide wire for insertion through the infusion guide wire and having a diameter sufficiently small to be passed through a lumen of said infusion guide wire, said leading guide wire having a sufficient length to pass through and protrude from a distal end of said infusion guide wire, and having a distal end capable of penetrating a wall of the right atrium of the subject's heart,

wherein said dual guide wire has sufficient flexibility to pass through a guide catheter into the right atrium of the subject's heart via a transvenous route and sufficient pushability to penetrate into the pericardial space through a wall of a right atrium of the heart without kinking.

56. (New) The dual guide wire of claim 55, wherein said dual guide wire has sufficient pushability to penetrate into the pericardial space through said wall of said right atrium of the heart without kinking while being aligned tangential to said wall of said right atrium.

57. (New) The dual guide wire of claim 55, wherein said infusion guide wire further comprises a radiopaque marker on its distal end.

58. (New) The dual guide wire of claim 55, wherein said guide catheter further comprises a radiopaque marker on its distal end.

59. (New) The dual guide wire of claim 55, wherein said leading guide wire further comprises a radiopaque marker on its distal end.

60. (New) The dual guide wire of claim 55, further including a locking device to fix a relative position of the leading guide wire relative to the infusion guide wire.

61. (New) The dual guide wire of claim 55, wherein said infusion guide wire has a lumen of sufficient diameter for passing a fiberoptic imaging probe into the pericardium.

62. (New) The dual guide wire of claim 55, wherein said infusion guide wire has a lumen of sufficient diameter for aspiration of fluid from the pericardial space to treat cardiac tamponade.

63. (New) The dual guide wire of claim 55, wherein said infusion guide wire is coaxial with a guide catheter upon insertion of said guide catheter into the right atrium.

64. (New) The dual guide wire of claim 55, wherein said dual guide wire further comprises a radiopaque marker on its distal end.

65. (New) The dual guide wire of claim 55, further including a locking device to fix a relative position of the leading guide wire relative to the infusion guide wire.

66. (New) A dual guide wire for transvenously accessing a pericardial space between a heart and its pericardium to perform a surgical procedure on the heart comprising:

an infusion guide wire; and

a leading guide wire insertable into the a right atrium of the heart through said infusion guide wire and having a distal end capable of penetrating a wall of the right atrium of the heart, wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability to penetrate the wall of the right atrium into the pericardial space without kinking,

wherein the dual guide wire may be used to perform a surgical procedure on the heart.

67. (New) The kit of claim 66, wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability to penetrate into the pericardial space through a wall of the right atrium of the heart without kinking while being aligned tangential to said wall.

68. (New) A dual guide wire for transvenously accessing a pericardial space between a heart and its pericardium comprising:

an infusion guide wire; and

a leading guide wire insertable into the heart through said infusion guide wire,

wherein said dual guide wire has sufficient pushability to penetrate into the pericardial space through a wall of a right atrium of the heart without kinking, and has sufficient steerability to be steered to any location within the pericardium.

69. (New) A dual guide wire for transvenously accessing a pericardial space between a heart and its pericardium for aspiration of fluid from the pericardial space to treat cardiac tamponade comprising:

an infusion guide wire for aspiration of fluid from the pericardial space to treat cardiac tamponade; and

a leading guide wire insertable into the heart through said infusion guide wire and having a distal end capable of penetrating a wall of a right atrium of the heart,

wherein said dual guide wire has sufficient pushability to penetrate the wall of the right atrium into the pericardial space without kinking.

70. (New) A dual guide wire for transvenously accessing a pericardial space between a heart and its pericardium to implant a surgical device within the heart comprising:

an infusion guide wire; and

a leading guide wire insertable into the heart through said infusion guide wire and having a distal end capable of penetrating a wall of a right atrium of the heart, wherein said infusion guide wire and said leading guide wire jointly have sufficient pushability to penetrate the wall of the right atrium into the pericardial space without kinking.

wherein the dual guide wire is adapted for implantation of a surgical device within the heart.

71. (New) The dual guidewire of claim 70, wherein the dual guide wire is adapted for implantation of the surgical device within a coronary artery of the heart.